AMENDMENTS TO THE CLAIMS

Please cancel claims 51, 98-99, and 101-103. Please amend claims 52 and 104 and 106 as shown below.

1-51. (canceled)

52. (previously presented) A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet ~~as recited in claim 51~~ comprising micronized progesterone, a non-effervescent excipient or diluent, and an effervescent, and retaining said tablet in said vagina for a time efficacious to deliver said progesterone to said patient.

53. (previously presented, allowed) A method according to claim 52, wherein said tablet contains at least 50 mg of micronized progesterone.

54. (previously presented) A method according to claim 53, wherein said placing of tablet is effected as part of a twice-daily dosing regimen.

55. (previously presented) A method for preparing a tablet for the vaginal administration of progesterone for systemic use, comprising the steps of:

(i) preparing a mixture consisting of water and micronized progesterone to obtain wetted micronized progesterone; and

drying said wetted micronized progesterone to obtain dry micronized progesterone;

(ii) mixing said dried micronized progesterone with at least one pharmaceutically acceptable excipient or diluent to form a second mixture; and

(iii) forming a tablet by direct compaction of said second mixture.

56. (previously presented) A method for preparing a tablet for the vaginal administration of progesterone for systemic use, comprising:

(i) mixing water with micronized progesterone to obtain wetted micronized progesterone in the absence of any other ingredient; and

drying said wetted micronized progesterone to form dry micronized progesterone;

(ii) mixing said dry micronized progesterone with

(a) a pharmaceutically acceptable non effervescent excipient or diluent and

(b) an effervescent to form a mixture; and

(iii) forming a tablet by direct compaction of said mixture.

57. (previously presented) A method according to claim 56 for preparing a tablet for the vaginal administration of progesterone for systemic use, wherein the step of mixing said dry micronized progesterone with (a) a pharmaceutically acceptable non effervescent excipient or diluent and (b) an effervescent comprises:

(i) sieving a first lubricant to obtain a sieved first lubricant;

(ii) mixing said dry micronized progesterone with said sieved first lubricant and a material selected from a first filler or a disintegrant to form a first mixture;

(iii) mixing a binder which binds dry particles with said first mixture to form a second mixture;

(iv) intimately mixing said effervescent and a first quantity of a second filler to form a third mixture;

(v) sieving said third mixture to obtain a sieved third mixture, and then intimately mixing said sieved third mixture and said second mixture to form a fourth mixture;

(vi) intimately mixing said fourth mixture with a second quantity of said second filler to form a fifth mixture;

(vii) sieving a second lubricant and a material selected from a saponificant or a third lubricant to obtain, respectively, sieved second lubricant and sieved third lubricant; and

(viii) intimately mixing said sieved second lubricant and said sieved third lubricant with said fifth mixture to form a sixth mixture.

58. (previously presented) A method according to claim 57, wherein said first lubricant is sieved through sieves having a pore size of between about 400 and 450 microns.

59. (previously presented) A method according to claim 58, wherein said first lubricant is sieved through sieves having a pore size of about 425 microns.

60. (previously presented) A method according to any of claim 57, wherein said third mixture is sieved through sieves having a pore size of between about 400 and 450 microns.

61. (previously presented) A method according to any of claim 58, wherein said third mixture is sieved through sieves having a pore size of between about 400 and 450 microns.

62. (previously presented) A method according to any of claim 59, wherein said third mixture is sieved through sieves having a pore size of between about 400 and 450 microns.

63. (previously presented) A method according to claim 60, where said pore size is about 425 microns.

64. (previously presented) A method according to claim 61, where said pore size is about 425 microns.

65. (previously presented) A method according to claim 62, where said pore size is about 425 microns.

66. (previously presented) A method according to claim 57, wherein said sieved second lubricant and said sieved third lubricant are sieved through sieves having a pore size of between about 100 and 150 microns.

67. (previously presented) A method according to claim 66, wherein said pore size is about 125 microns.

68. (previously presented) A method according claim 57, wherein said first lubricant is silicon dioxide (colloidal anhydrous silica).

69. (previously presented) A method according to claim 57, wherein said material selected from a first filler or a disintegrant is a starch exhibiting good flow properties.

70. (previously presented) A method according to claim 69, wherein said starch is derived from corn (maize), potatoes or wheat.

71. (previously presented) A method according to claim 60 wherein said starch is cornstarch.

72. (previously presented) A method according to claim 57, wherein said binder which binds dry particles is polyvinylpyrrolidone (Povidone).

73. (previously presented) A method according to claim 72, wherein said binder which binds dry particles is Povidone K 30.

74. (previously presented) A method according to claim 57, wherein said second filler is derived from a natural source.

75. (previously presented) A method according to claim 74, wherein said second filler is selected from lactose or a composition composed principally of lactose.

76. (previously presented) A method according to claim 57, wherein said first portion and said second portion of said second filler are of generally the same size.

77. (previously presented) A method according to claim 57, wherein said effervescent is prepared prior to said intimate mixing of said first portion of said second tiller with said effervescent.

78. (previously presented) A method according to claim 57, wherein said effervescent is prepared in situ as part of said intimate mixing of said first portion of said second filler with said effervescent.

79. (previously presented) A method according to claim 57, wherein said intimate mixing of said first portion of said second filler with said effervescent comprises non intimately mixing said first portion of said second filler with said effervescent and passing the resultant non intimately mixed mixture through a sieve having an average pore size between about 400 and 450 microns, to obtain said third mixture.

80. (previously presented) A method according to claim 79, wherein said intimate mixing of said first portion of said second filler with said effervescent comprises non intimately mixing said first portion of said second filler with said effervescent and passing the resultant non intimately mixed mixture through a sieve having an average pore size of about 425 microns diameter to obtain said third mixture.

81. (previously presented) A method according to claim 57, wherein said intimate mixing of said second mixture with said third mixture to obtain said fourth mixture is accomplished by non intimately mixing said second mixture with said third mixture to obtain a non intimately mixed mixture and sifting said non intimately mixed mixture through a sieve having an average pore size between about 400 and 450 microns to obtain said fourth mixture.

82. (previously presented) A method according to claim 81, wherein said intimate mixing of said second mixture with said third mixture to obtain said fourth mixture is accomplished by non intimately mixing said second mixture with said third mixture to obtain a non intimately mixed mixture and sifting said non intimately mixed mixture through a sieve having an average pore size of about 425 microns diameter to obtain said fourth mixture.

83. (previously presented) A method according to claim 57, wherein said second lubricant is selected from magnesium stearate, talc, sodium lauryl sulfate, and phosphates known in the art to function as lubricants.

84. (previously presented) A method according to claim 83, wherein said lubricant is magnesium stearate.

85. (previously presented) A method according to claim 57, wherein said material selected from a saponificant or a third lubricant is sodium lauryl sulfate.

86. (previously presented) A method according to claim 56, wherein said effervescent is a mixture of a pharmaceutically acceptable carboxylic or dicarboxylic acid and a pharmaceutically acceptable salt of HCO3.

87. (previously presented) A method according to claim 86, wherein said pharmaceutically acceptable carboxylic or dicarboxylic acid is selected from adipic acid or tartaric acid.

88. (previously presented) A method according to claim 86, wherein said pharmaceutically acceptable salt of HC03 is as sodium bicarbonate.

89. (previously presented) A method according to claim 86, wherein said pharmaceutically acceptable carboxylic or dicarboxylic acid and said bicarbonate are present in an amount providing a molar excess of COOH groups.

90. (previously presented) A method according to claim 86, wherein said effervescent comprises a mixture ofadipic acid and sodium bicarbonate.

91. (previously presented) A method according to claim 56, wherein said effervescent comprises between about 6 and 10 wt.%.

92. (previously presented) A method according to claim 55 wherein the amount of water mixed with said micronized progesterone is between about 25 and 28 wt.% of the amount of micronized progesterone.

93. (previously presented) A method according to claim 92, wherein the amount of water mixed with said micronized progesterone is about 28 wt.% of the amount of micronized progesterone.

94. (previously presented) A method according to claim 55, wherein said water is added to said micronized progesterone at rate of between about 6 to 9 ml per minute.

95. (previously presented) A method according to claim 55, wherein said water is mixed with said micronized progesterone at a mixing speed of between about 25 33.3 rpm.

96. (previously presented) A method according to claim 55, wherein said drying of said wetted micronized progesterone is done at a temperature of between about 55°C and about 60°C.

97. (previously presented) A method according to claim 55, wherein all of said mixing steps are carried out at a temperature of between about 15°C and 30°C.

98. (canceled)

99. (canceled)

100. (previously presented, allowed) A tablet prepared by the steps of:

(i) first mixing water with micronized progesterone to obtain wetted micronized progesterone; and

drying said wetted micronized progesterone to a humidity content of substantially 0% to form substantially dry micronized progesterone;

(ii) sieving a first lubricant to obtain a sieved first lubricant;

(iii) mixing said substantially dry micronized progesterone with said sieved first lubricant and a material selected from a first filler or a disintegrant to form a first mixture;

(iii) mixing a binder which binds dry particles with said first mixture to form a second mixture;

(iv) intimately mixing an effervescent and a first quantity of a second filler to form a third mixture;

(v) sieving said third mixture to obtain a sieved third mixture, and then intimately mixing said sieved third mixture and said second mixture to form a fourth mixture;

(v) intimately mixing said fourth mixture with a second quantity of said second filler to form a fifth mixture;

(vi) sieving a second lubricant and a material selected from a saponificant or a third lubricant to obtain, respectively, sieved second lubricant and sieved third lubricant;

(viii) intimately mixing said sieved second lubricant and said sieved third lubricant with said fifth mixture to form a sixth mixture; and

(ix) tabletting said sixth mixture by direction compaction to form a tablet.

101. (canceled)

102. (canceled)

103. (canceled)

104. (currently amended) A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet ~~as recited in claim 98~~, wherein said tablet is prepared by the steps of:

(i) preparing a mixture consisting of water and micronized progesterone to obtain wetted micronized progesterone; and

drying said wetted micronized progesterone to obtain dry micronized progesterone;

(ii) mixing said micronized progesterone with at least one pharmaceutically acceptable excipient or diluent to form a second mixture; and

(iii) forming a tablet by direct compaction of said second mixture said tablet having a T_{max} upon disintegration of at least about three hours;

and retaining said tablet in said vagina for a time efficacious to deliver said progesterone to said patient.

105. (previously presented) A method according to claim 104, wherein said tablet contains at least 50 mg of micronized progesterone.

106. (currently amended) A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet ~~as recited in claim 99~~, wherein said tablet is prepared by the steps of:

(i) mixing water with micronized progesterone to obtain wetted micronized progesterone in the absence of a pharmaceutically acceptable excipient or diluent; and

drying said wetted micronized progesterone to form dry micronized progesterone;

(ii) mixing said dry micronized progesterone with

(a) a pharmaceutically acceptable non effervescent excipient or diluent and

(b) an effervescent to form a mixture; and

(iii) forming a tablet by direct compaction of said mixture,

the tablet having a T_{max} upon disintegration of at least about three hours;

and retaining said tablet in said vagina for a time efficacious to deliver said progesterone to said patient.

107. (previously presented) A method according to claim 106, wherein said tablet contains at least 50 mg of micronized progesterone.

108. (previously presented) A method according to claim 106, wherein said placing of tablet is effected as part of a twice daily dosing regimen.

109. (previously presented) A method for preparing a tablet for vaginal administration which comprises

(i) mixing water with micronized progesterone to obtain wetted micronized progesterone prior to adding any other ingredients; and

drying said wetted micronized progesterone;

(ii) mixing a pharmaceutically acceptable excipient or diluent with said micronized progesterone after said drying to form a tabletting mixture; and

(iii) directly compacting said tabletting mixture to form said tablet.

110. (previously presented) A method for preparing a tablet for the vaginal administration of progesterone for systemic use, comprising the steps of:

(i) preparing a mixture consisting essentially of water and micronized progesterone to obtain wetted micronized progesterone; and

drying said wetted micronized progesterone to obtain dry micronized progesterone;

(ii) mixing said dried micronized progesterone with at least one pharmaceutically acceptable excipient or diluent to form a second mixture; and

(iii) forming a tablet by direct compaction of said second mixture.

111. (previously presented) A method for preparing a tablet for the vaginal administration of progesterone for systemic use, comprising:

(i) mixing water with micronized progesterone to obtain wetted micronized progesterone in the absence of a pharmaceutically acceptable excipient or diluent; and

drying said wetted micronized progesterone to form dry micronized progesterone;

(ii) mixing said dry micronized progesterone with

(a) a pharmaceutically acceptable non effervescent excipient or diluent and

(b) an effervescent to form a mixture; and

(iii) forming a tablet by direct compaction of said mixture.

112. (previously presented) A method of claim 56, wherein said effervescent comprises about 8-wt.% of the tablet.